REMARKS

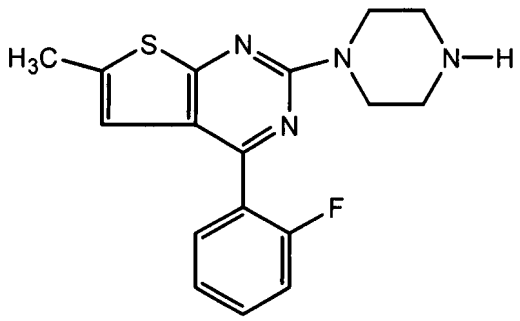
Amendments to the Claims

Claims 1, 3, 7-15 and 21 have been canceled. Claim 16 has been amended. New Claims 71-75 have been added.

Claim 16, as amended, recites "a method of treating nausea, vomiting, retching or any combination thereof in a human subject in need thereof, wherein the nausea, vomiting, retching or any combination thereof is caused by a cancer chemotherapeutic agent." Support is found in the specification, for example, at page 6, lines 7-8; page 8, lines 4-6; and page 33, lines 20-23 and the exemplification starting at page 49.

Claim 16 has also been amended to recite that about 0.001 mg to about 1000 mg per day of a compound represented by Formula II is administered. New Claims 71-73 also specify the amount of active compound being administered. For example, new Claim 71 recites "about 0.05 mg to about 500 mg per day," new Claim 72 recites "about 0.03 mg to about 300 mg per day," and new Claim 73 recites "about 0.02 mg to about 200 mg per day." Support is found in the specification, for example, at page 42, lines 7-24.

Further, Claim 16 has been amended to recite that the compound is represented by Formula II:



II

or a pharmaceutically acceptable salt thereof. Support is found in the specification, for example, at page 2, lines 9-15.

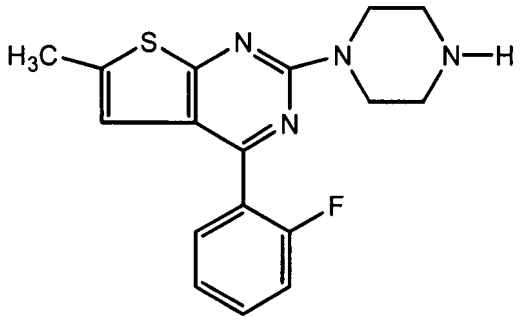
New Claim 74 recites "wherein said administering is oral." Support is found in the specification, for example, at page 37, lines 2-3.

New Claim 75 recites "wherein said pharmaceutically acceptable salt is a hydrochloride salt." Support is found in the specification, for example, at page 44, lines 16-26.

Entry of the amendments into the application is respectfully requested.

Amendments to the Abstract

The Abstract has been amended to recite "The invention relates to a method of treating nausea, vomiting, retching or any combination thereof in a subject in need of treatment, wherein the nausea, vomiting, retching or any combination thereof is caused by a cancer chemotherapeutic agent. The method comprises administering to a subject in need of treatment a therapeutically effective amount of a compound represented by Formula II:



II

or a pharmaceutically acceptable salt thereof." Support is found in the specification, for example, at page 2, lines 9-15; page 6, lines 7-8; 8, lines 6-7; and page 33, lines 20-23.

Entry of the amendments into the application is respectfully requested.

Rejection of Claims 1, 3, 7-16 and 21 Under 35 U.S.C. §112, first paragraph

The Examiner has rejected Claims 1, 3, 7-16 and 21 under 35 U.S.C. §112, first paragraph as lacking enablement because "the claims are broad both in the recitation of various causes of nausea, vomiting, retching or any combination thereof and with regard to the numerous possible compounds that are encompassed in instant formula I."

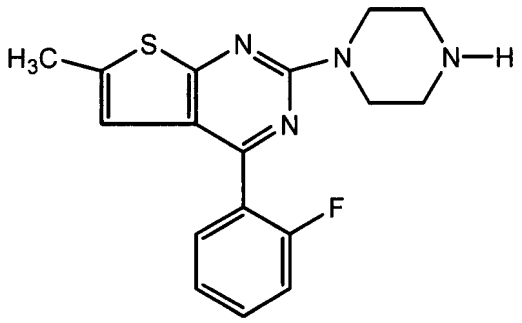
Applicants respectfully disagree. However, in an effort to expedite prosecution, Applicants have canceled Claims 1, 3, 7-15 and 21. In addition, independent Claim 16, as amended, is now directed to the treatment of nausea, vomiting, retching or any combination thereof:

(a) caused by a cancer chemotherapeutic agent;

(b) treated with the specific compound of Formula II; and

(c) administered in specified dose.

More specifically, Claim 16 has been amended to recite "a method of treating nausea, vomiting, retching or any combination thereof in a human subject in need thereof, wherein the nausea, vomiting, retching or any combination thereof is caused by a cancer chemotherapeutic agent, comprising administering to said subject about 0.001 mg to about 1000 mg per day of a compound represented by Formula II:



II

or a pharmaceutically acceptable salt thereof."

On page 5 of the Final Office Action, the Examiner notes that the example in the specification "is limited to the administration of a single compound (MCI-225) of the present invention wherein the cause of emesis is cancer chemotherapy-induced." The pending claims, as amended, are directed to the type of nausea, vomiting, retching or any combination thereof exemplified and the compound administered in the example, because the claims now recite:

(a) nausea, vomiting, retching or any combination thereof is caused by a cancer chemotherapeutic agent;

(b) treated with the specific compound of Formula II; and

(c) administered in specified dose.

As such, Applicants' invention, particularly as amended, meets the requirements of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

Provisional Rejection of Claims 1, 3, 7-16 and 21 Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner has provisionally rejected Claims 1, 3, 7-16 and 21 under the judicially created doctrine of obviousness-type double patenting over Claims 1-3 of U.S. Patent No.: 7,094,786 and Claims 71-158 of USSN 10/846,978.

Applicants note this rejection and, to expedite prosecution, will file a terminal disclaimer upon indication that the only remaining rejections are the Double Patenting rejections.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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